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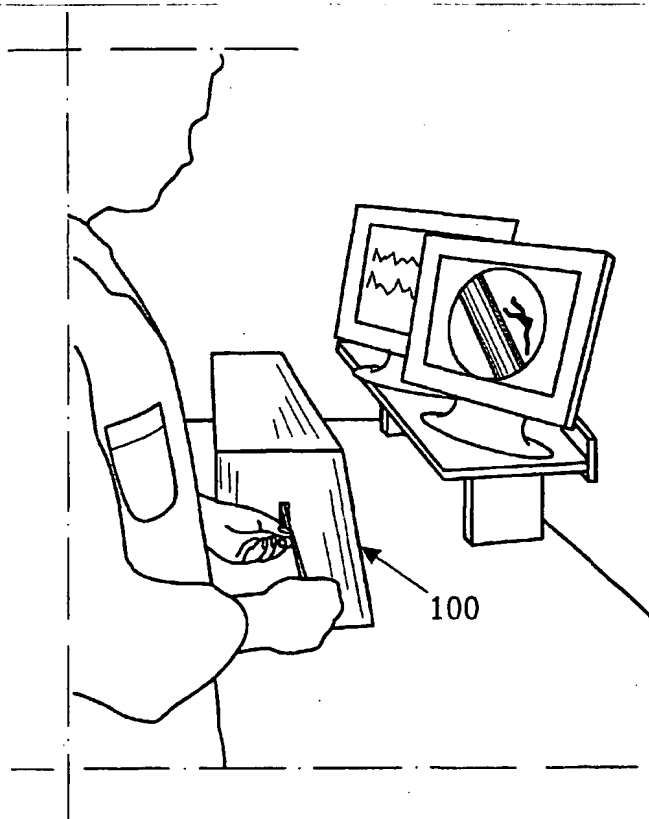
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(54) Title: **AN INTERVENTIONAL SIMULATION DEVICE**



(57) Abstract: The present invention relates to a device (100) in a simulation system for simulating an interventional operation. The device (100) is arranged to receive a number of real instruments, preferably at least two. The device (100) comprises a number of moveable carriages (16A-16C) corresponding to the number of the real instruments. The device (100) further comprises a track (20) and an interconnecting member (26). The interconnecting member (26) interconnects the carriages (16A-16C) serially. Each carriage (16A-16C) is provided with an opening for enabling reception of the instruments. Each carriage (16A-16C) further comprises members to receive and lock at least one instrument, and members for receiving a movement from the instrument and generating a force, fed back to the instrument with respect to a simulation characteristic.

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TITLE

AN INTERVENTIONAL SIMULATION DEVICE

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TECHNICAL FIELD

The present invention relates to a device in a simulation system for simulating an interventional operation and most preferably endovascular operations.

10 BACKGROUND OF THE INVENTION

Principles of adult education, tenets of experiential learning, and theories addressing the development of expertise have all underscored the critical role experience plays in the learning process.

- 15 State-of-the-art simulations can be successfully included in contemporary surgical and medical education to offer trainees and practicing physicians the requisite learning experiences based on these educational underpinnings. All learners can be offered opportunities to acquire the essential skills and to achieve specified competency levels based on standardized learning experiences. Simulations can be used to facilitate learning
- 20 through the evaluation of performance and provision of immediate, individualized, and detailed feedback. Simulations offer controlled settings that allow repetition until the defined performance levels are achieved, decrease stress levels of learners, increase the confidence levels of learners, and increase safety in real settings by assuring the achievement of technical competence prior to work on patients.

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Practicing physicians can improve their skills and can learn new procedures emerging as a result of advances in science and technology through educational interventions involving the use of simulations. In addition, the use of simulations can help address practical issues, such as the demands on faculty time, by providing trainees the opportunities for

30 independent learning and practice. The current emphasis on accountability and on assurance of the quality of health care may also be addressed through the use of such simulations and data on outcomes can be used to assure the public of the competence of physicians.

- 35 Simulations should be considered an essential part of every contemporary educational program that addresses technical skills development. They can be used to ensure effective teaching and learning, to provide valid and reliable means of assessment of the skills of learners, to yield information on specific weaknesses that require improvement, and to create individual profiles of the technical ability of learners. In order to achieve the desired

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results, specific curricula should be developed based on principles of adult education, experiential learning, and effective feedback. Such simulations may also be used in programs of continuing professional education and certification.

- 5 The initial investment of resources needed for the development and acquisition of simulations and for the creation of training programs that incorporate them effectively in educational models is readily offset by the numerous advantages resulting from expeditious performance of procedures in the operating room, enhancement of patient safety, and decrease in the faculty time needed to teach learners various technical skills.
- 10 Such simulations may also be used to assess the effectiveness of educational efforts and even to select individuals for training. Thus, the simulations have the potential to make a major impact on programs of surgical and medical education of the future.

- As a result of the rapid developments within the computer technique, simulations,
- 15 especially for the purpose of surgical and medical education, have improved considerably. However, the presently known apparatus and methods do not allow a full range simulation of different instruments used and methods.

- United States Patent No. 6,106,301 discloses an interventional radiology interface
- 20 apparatus and method interfaces peripherals in the form of mock medical instruments to a medical procedure simulation system to enable performance of a medical procedure on a virtual patient. The interface apparatus includes a guide wire, catheter and sheath, an injection syringe, an inflation syringe and a foot switch to realistically simulate the instruments utilized during an actual medical procedure. A user manipulates guide wire,
- 25 catheter and sheath peripherals to traverse an arterial network toward a simulated blockage shown on the medical procedure simulation system display. The foot switch controls the display to provide a fluoroscope image showing the position of the guide wire, catheter, sheath and blockage within the arterial network. The injection syringe may be manipulated to simulate injections of contrast fluid or other pharmaceutical substances
- 30 through the catheter or sheath into the virtual patient. When a guide wire is positioned past the simulated blockage within the arterial network, the catheter is exchanged for a balloon-tipped angioplasty catheter, and the inflation syringe is manipulated to simulate inflation of the balloon to reduce the blockage. In addition, the interface apparatus may apply force feedback to the guide wire and catheter to simulate forces encountered by
- 35 these instruments during an actual medical procedure. The interface apparatus measures peripheral manipulation and transfers these measurements via a processor to the medical procedure simulation system to enable simulation of the medical procedure.

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- United States Patent No. 6,267,599 discloses a system for producing highly realistic, real-time simulated operating condition for interactive training of persons to perform minimally invasive surgical procedures involving implements that are inserted and manipulated through small incisions in the patient. The virtual environment for this training system
- 5 includes a housing with small opening. An implement simulating a surgical implement is inserted into the opening and manipulated relative to the housing. A movement guide and sensor assembly monitors the location of the implement relative to the housing and provides data about the implement's location and orientation within the housing.
- 10 The reported data is interpolated by a computer processor, which utilizes a database of information representing a patient's internal landscape to create a computer model of the internal landscape of the patient. With reference to this computer model, the processor controls the occurrence of force feedback opposing the motion of the implement. A two-dimensional image representing the implement, as it would appear within the patient is
- 15 generated by a processor-controlled video imaging system based on the computer model of the patient's internal landscape. This computer image of the implement is then merged with a video image loop of a patient's internal landscape as it appears through a heartbeat and breathing cycle, and the merged image is displayed on a video display.
- 20 The combined elements of real-time visual representation and interactive tactile force feedback provide a virtual training simulation with all elements of actual operation conditions, minus a live patient. The system according to the invention described in US 6,267,599 cannot be used for simulating several instruments simultaneously and in real time.
- 25 WO 99/39317 describes an interface device for handling several instruments through the same interface for simulating instrumental movement and rotation in a medical procedure simulation system. This system uses specially manufactured mock instruments that fit into the interface device and the instruments will be engaged and locked by carriage
- 30 assemblies prepared to receive their specific respective instrument type. The solution with mock instruments and special order of insertion makes this system unrealistic and complex for the user, since the user needs to know the configuration of the carriage assemblies and the correct insertion order according to this configuration.
- 35 **SUMMARY OF THE INVENTION**
- One object according to the best embodiment of the present invention is to provide an interface device for simulation of interventional operations and most preferably endovascular operations, which allows simultaneous simulation of different instruments. The device of the preferred embodiment of the invention provides more accurate control.

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Other advantages according to the best embodiments include:

- The user can work with at least three independent instruments at the same time.
 - Real Instruments can be used.
 - Through a better feedback system a more realistic feeling is obtained.
- 5 • Instruments can be inserted and withdrawn as in real operations, without special interaction or control from the user.

For these reasons, the initially mentioned device is arranged to receive a number of real instruments, preferably at least two real instruments. The device comprises: a number of
10 moveable carriages corresponding to the number of the real instruments, a track, and an interconnecting member. The interconnecting member interconnects the carriages serially. Each carriage is provided with an opening for enabling reception of the instruments. Each carriage further comprises members to receive and lock at least one instrument. Each carriage further comprises members for receiving a movement from the instrument and
15 generating a force, fed back to the instrument with respect to a simulation characteristic.

In one preferred embodiment of the invention, the opening is provided within the interconnecting member.

20 In another preferred embodiment, the interconnecting member is a telescopic pipe, allowing insertion of nested instruments.

In a further preferred embodiment each carriage comprises a detecting arrangement for detecting the type of the instrument inserted through the interconnecting member, which
25 simplifies the handling of the instrument.

In yet a further preferred embodiment, the device is connected to a control unit to measure the movement of the carriages and control the movement by means of a speed control loop and a position control loop, to provide accurate feedback.

30

In one preferred embodiment, the carriages are arranged to move along the track.

In a further preferred embodiment, the carriage has an actual position and a simulated position. The actual carriage position determines the simulated carriage position from a
35 scale table.

In another preferred embodiment, the carriage is connected through a transmission for driving along the track. The carriage is provided with a crank block, which is arranged in a torque wheel. The crank block is provided with a mating surface, which is pressed towards

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a collet that grips the instrument wire, in a nested manner.

In another preferred embodiment, the force between a suspended plate and a chassis. The chassis is arranged on the carriage, is gauged by means of a force sensor.

5

In another preferred embodiment, the carriage is provided with a detecting member, which detects presence of an instrument in the carriage.

In a further preferred embodiment, the detecting member is arranged to detect the type of
10 each instrument.

In another preferred embodiment, the instruments are categorized into the types with respect to at least one of the following characteristics: thickness, color, structure, material, identity and/or bar code.

15

In yet another preferred embodiment, the detecting member is an optical sensor.

In yet another preferred embodiment, a first interconnecting member is arranged between the opening and the first carriage. A second interconnecting member is arranged between
20 the first carriage and the second carriage. A third interconnecting member is arranged between the second carriage and the third carriage.

In another preferred embodiment, the device comprises a processing unit for measuring a longitudinal movement and a movement of rotation of the instrument.

25

In another preferred embodiment, the device comprises a processing unit, which provides force feedback in the longitudinal direction and in the direction of rotation, of the instrument.

30 Most preferably, the instruments are real instruments, with one simulated end. This allows testing different commonly available instruments.

In yet another preferred embodiment, the device comprises a locking member, for clamping an instrument. The locking member is attached to a central wall. The locking
35 member may comprise a member for applying a torque.

In yet another preferred embodiment, the crank block is provided inside a torque wheel. The crank block moves in a longitudinal direction and is fixed in the direction of rotation,

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relatively to the torque wheel.

The invention also relates to a method of simulating an interventional operation by means of a device in a simulation system is used. The device is arranged to receive a number of
5 instruments, preferably at least two instruments. The device comprises a number of moveable carriages corresponding to the number of the instruments, a track and an interconnecting member. The method comprises the steps of inserting a number of instruments into the device, receiving the instruments by each carriage, which are interconnected serially, by receiving and locking at least one instrument. Each carriage
10 further comprises members for receiving a movement from the instrument and generating a force fed back to the instrument with respect to a simulation characteristic.

According to one aspect of the invention, a simulator system, preferably an interventional procedure simulator system is provided. The simulator system comprises at least a first
15 and a second displaceable member and a control system. The control system comprises: a first controller ($F1(s)$), controlling the speed of the first displaceable member (16A-16C) towards a set value (CDV). The control system further comprises a second controller ($F2(s)$), for combining an error in a position (CAP) and a speed of the second, previous displaceable member (PCAV) to a set speed for the first member. The second controller
20 ($F2$) controls $CDV = C1 * (CAP - PCAP) + C2 * PCAV$, wherein $C1$ and $C2$ are constants.

According to another aspect of the invention, a simulator system, preferably an interventional procedure simulator system is provided. The simulator system comprises an arrangement for receiving an instrument to be simulated. The arrangement comprises
25 identification means for identifying the instrument.

In yet another preferred embodiment, the arrangement for detecting an instrument, comprise at least one IR diode and at least one IR phototransistor.

30 In one preferred embodiment the identification means consists of at least one of thickness, color, structure, material of the instrument, identity and/or bar code.

According to another aspect of the invention a simulator system, preferably an interventional procedure simulator system is provided. The simulator system comprises
35 members to receive and lock an instrument to be simulated, and a control unit comprising a force sensor. The control unit controls towards a demand force value, DF. A force that a user experiences in the instrument is measured with the force sensor and a signal from the force sensor is fed back in a force feedback control loop towards a set force.

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According to another aspect of the invention a simulator system, preferably an interventional procedure simulator system, an arrangement for generating a resistance in a simulated instrument is provided. The arrangement comprises a control unit and a force sensor. The arrangement further comprises a force feedback control loop for controlling an actuator device for driving an instrument receiver member in a direction. The arrangement further comprises an inner force control loop. The force sensor is arranged for measuring the resistance. A signal from the force sensor is fed back in the inner force control loop that controls, with a loop-amplification, K , provided by the control unit, towards a set force value, SF , provided by the control unit and the inner force control loop controlling the actuator.

In one preferred embodiment, the control unit controls the loop amplification, K , to achieve a resistance.

15 In one preferred embodiment, the control unit controls the set force, SF , to achieve a resistance.

According to another aspect of the invention a simulator system, preferably an interventional procedure simulator system is provided. The simulator system comprises an arrangement for generating a resistance in a simulated instrument. The simulator system further comprises an arrangement for receiving and fixing a part of an instrument in a device for measuring instrument movement and feeding back a force to the instrument. The arrangement comprises a member for clamping the instrument. The arrangement comprises a crank block, which is arranged in a torque wheel, the crank block is movable in a longitudinal direction inside the torque wheel. The crank block is provided with a mating surface, which is pressed towards a collet that grips the instrument part.

BRIEF DESCRIPTION OF THE DRAWING

In the following the inventions will be described in a non-limiting way with reference to the best embodiment of the invention, in conjunction with enclosed drawings, in which:

Fig. 1 shows a general overview of the device according to the present invention, when used,

Fig. 2 shows a sectional view of the device,

Fig. 3 shows the carriages schematically,

35 Fig. 4 shows a sectional view of a carriage,

Fig. 5 shows a lateral view of a carriage,

Fig. 6 shows a front view of the optic sensor,

Fig. 7 shows a lateral view of the locking member,

Fig. 8 shows a block diagram of the control system,

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Fig. 9 shows a block diagram of the passive force feedback loop, and
 Fig. 10 shows a block diagram of the active force feedback loop.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

- 5 In the following, the best embodiment of the invention and some modifications thereof, will be described in detail and with reference to the enclosed drawings. Some examples of other possible embodiments will also be described.

The interface device 100 according to the best embodiment of the present invention, as
 10 shown in Fig. 3, comprises:

- Processing units 10 arranged on corresponding Printed Card Boards, PCBs.
- A communication unit 12.
- A power supply 14.
- At least three carriages 16A-16C. Each carriage 16 having the same technical
 15 features. The carriages 16A-16C are arranged to lock different types of
 instruments, which is described later on.
- Motors and transmission 18 for driving the carriages 16A-16C.
- A track 20 on which the carriages 16A-16C can move. In this embodiment it is a
 common track, but in other embodiments it can for example be three tracks in
 20 parallel or the like.
- An opening 22 provided with entry pipes 24.
- Interconnecting members 26, in form of telescopic pipes 26A-26C, see Fig. 2.
- A cover 28.
- A control unit 30, in form of software in a PC.

25

Each carriage 16A-16C comprises:

A chassis 32 provided with wheels 34. In other embodiments the chassis can be provided with runners, slide bushings or the like. The chassis 32 is attached to a transmission 18, preferably a gear belt transmission, through a connector pin for driving along the track 20.

- 30 In other embodiments chain transmission, wire transmission or pneumatic cylinder transmission can be used. A suspended plate 38 is attached to the chassis 32 through a spring suspension. One of the springs is a sensor, in form of a load cell, which measures the force between the suspended plate 38 and the chassis 32. This sensor is henceforth called the force sensor 40. A substantially, centrally provide wall 42, is arranged on the
 35 suspended plate 38, see Fig 4 and Fig. 5.

The function of each carriage 16A-16C is to detect when an instrument has passed through the carriage, by means of a detecting member 48, determine the type of the instrument and if a decision is made from the control unit 30, to lock the instrument. The locking

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mechanism, further described later on, is activated by the locking member 44 to provide a locking.

- Connections for the interconnecting member 26 are arranged at the opening 22 and the outlet 46. In the best embodiment of the present invention the interconnecting members are in form of telescopic pipes, but can also be in form of elastic pipes or the like, for example made of rubber or non-rigid plastic. The interconnecting members 26 make it possible to operate with three interacting nested instruments. The interconnecting members 26 moves between the carriages 16, see Fig. 2. The first interconnecting member 26A, is arranged between the opening 22 and the first carriage 16A, the second interconnecting member 26B is arranged between the first carriage 16A and the second carriage 16B and the third interconnecting member 26C is arranged between the second carriage 16B and the third carriage 16C.
- 15 The detecting member 48, in form of an optical sensor, detects presence of an instrument in the carriage 16. The optical sensor 48 can furthermore determine which type the instrument belongs to. The instruments are categorized into said types according to thickness, and/or other identity signs, for example color, structure and/or material of the instrument. In another embodiment the instruments can be provided with bar codes and the detecting member can be arranged with a bar-code reader. The detecting member 48 is arranged at the outlet 46 and comprises an IR diode 104 and an IR phototransistor 106, which are arranged at each side of the tool passage 108, see Fig. 6, through which the instruments passes. The light travels from the IR diode 104 to the IR phototransistor 106 through the light channel 110. The IR diode 104 emits IR light through voltage supply and current limiting with a resistance. The light is led via the light channel 110 to the IR phototransistor 106, which is more or less permeable for current, depending on how much light that reaches it. When there is no instrument in the tool passage 108, a maximal amount of light reaches the IR phototransistor 106. When an instrument is present in the light channel 110, it blocks the light flow to the IR phototransistor 106 and hence less light reaches it. The more light that reaches the IR phototransistor 106, the more current the IR phototransistor 106 let through and the higher the voltage over the resistance gets. An A/D transducer measures that voltage and the measurement test result is sent to the control unit 30.
- 35 The locking member 44 is arranged to clamp up an instrument, and is attached in the central wall 42. The same locking member 44 can provide a torque on an instrument, such that it provides force-feedback to the instrument in the direction of rotation.

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Subsequent to the detection and locking of the instrument/instruments is/are, the carriage 16 follows the users movement of the instrument. This is done by means of the transmission 18 and the control electronic, and is so controlled that a demand force is obtained from the control unit 30. The force-feedback is further described later on.

5

Fig. 7 shows the locking member 44 according to the best embodiment of the present invention. A central unit 50 with a torque wheel 52 is attached to the central wall 42 by means of a bearing, for example a ball bearing or a roller bearing. The torque wheel 52 is provided with a gear ring 54. A torque motor 56 with a motor hub 58 and a torque motor gear wheel 60, is arranged to drive the torque wheel 52. A lock wheel 62, is attached to the torque wheel 52 through a bearing, for example a ball bearing, roller bearing, needle bearing or a polymer bush. Further, a lock motor 64, with motor hub 66 and lock motor gear wheel 68, is arranged to drive the lock wheel 62. The locking member 44 further comprises a collet 70, which grips the instrument, and a collet seat 72, in which the collet 15 70 is arranged.

A crank block 74, which is arranged inside the torque wheel 52, can move in a longitudinal direction, but is fixed in the direction of rotation, relatively the torque wheel 52. Said crank block 74 is provided with wings. The wings run in a guide track, which is arranged in the torque wheel 52. The crank block 74 is provided with a mating surface, which is pressed 20 towards the collet 70 that grips the instrument wire. Instead of the crank block 74 other chucking principles can be used.

The locking member 44 further comprises an inner, lock wheel 62, which is attached 25 through bearings, for example ball bearings, needle bearings or the like, to the outer, torque wheel 52. The torque wheel 52 and the lock wheel 62, respectively, are provided with gear rings 54. The lock wheel 62 rotates inside the torque wheel 52 and is provided with a thread. The thread affects the crank block 74, which is fixed in the direction of rotation in the torque wheel 52, but runs freely in longitudinal direction. The collet 70 is 30 provided at the back edge of the lock wheel 62. The entire central unit 50 is arranged with two openings 22 in the center, through which the instrument can pass.

Two motors, the torque motor 56 and the lock motor 64, are fixed to the central wall 42. The motor axis are provided with motor gear wheels 60, 68, which goes against the gear 35 rings 54 of the torque motor 56 and the lock motor 64.

In the initiation sequence of the interface device, the carriages 16 are positioned closely in a row and towards the instrument entrance side. The user inserts an instrument or a tool in the entry pipe 24, through the first interconnecting member 26A, into the first carriage

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16A and through its central unit 50 and out through its outlet 46 there the detecting member, in form of e.g. an optical sensor 48 detects the instrument's presence and type. The control unit 30 decides from the detected instrument type, whether to lock the instrument or not. If the first carriage 16A does not lock the instrument, the instrument
5 passes through the first carriage 16A and out into the second interconnecting member 26B and further towards the second carriage 16B.

If the first carriage 16A locks the instrument, the locking sequence starts. Thus, the torque wheel 52 is fixed through the torque motor 56. After that the lock wheel 62 is rotated by
10 means of the lock motor 64, so that the crank block 74 is pressed towards the collet 70, which clamps around the instrument. The locking member 44 and the suspended plate 38 are consequently fixed to the instrument.

After the locking sequence follows the force and torque control. A force controller control,
15 with high frequency from the force sensor 40, the position of the chassis 32 so that a given set force is maintained in the force sensor 40. The force is transferred to the instrument. The user feels this set force in the instrument, which gives force-feedback in the longitudinal direction. The torque control sets out a set torque, by means of the torque motor 56, which causes force-feedback in the direction of rotation. The set force and set
20 torque are determined from the simulation. Information about the position of the instruments in the longitudinal direction and in the direction of rotation is sent continuously to the simulation unit 90.

If the user withdraws the instrument, so that the carriage 16 passes its initial position, the
25 unlocking sequence starts. The unlocking sequence is carried out in a reversed order as the locking sequence. After the unlocking sequence, the instrument runs freely in the carriage 16.

All the carriages 16A-16C operate in the same way. An unlocked carriage follows the
30 nearest previous carriage's movements in a longitudinal direction along the track 20. To make the movement of the carriage flexible and reduce the control error, an inner, speed control loop 86 and an outer, position control loop 88 are used. The purpose of the speed control loop 86 is to control the speed of the carriages 16 with respect to each other. The purpose of the position control loop 88 is to keep the distance of the carriage 16 to
35 previous carriage 16 constant.

The block diagram of Fig. 8 shows the control system $G(s)$. The system $G(s)$ represents one of the carriages (16A-16C) driven by its longitudinal motor. $F1(s)$ is a controller, which controls the speed of the carriage towards a set value, Carriage Demand Velocity, CDV. $F1$

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is placed in one of the processor units 10 in the carriage 16. F1 gives a motor force to the longitudinal motor of the carriage 16.

F2(s) is a controller, which is placed in the control unit 30, that is, in the PC. F2 combines the error in position, (Demand position - Carriage Actual Position, CAP) and the speed of previous carriage 16, (Previous Carriage Actual Velocity, PCAV) to a set speed for the carriage 16.

F2 controls $CDV = C1*(CAP-PCAP) + C2*PCAV$

10

wherein:

CDV = Carriage Demand Velocity

CAP = Carriage Actual Position

PCAP = Previous Carriage Actual Position

15 PCAV = Previous Carriage Actual Velocity

C1 and C2 are constants

When the carriage 16 has locked an instrument or a tool, the control unit 30 controls towards a demand force value, DF. If the chosen demand force value for example is zero, the carriage 16 will be controlled so that the user experiences zero force in the instrument. If the user for example passes through a stenosis in a vessel, in the simulation, the user will feel a resistance in the instrument and then a desired demand force value is set to that resistance. To accomplish this, the force sensor 40 and the force feedback control loop 102 controls the longitudinal motor. The longitudinal motor drives the carriages 16A-16C along the track 20. The force that the user experience in the instrument is measured with the force sensor 40. The signal from the force sensor 40 is fed back in a control loop towards a set force, SF. This force feedback control loop 102 is shown in Fig. 9.

There are two types of force feedback that can be used "passive force feedback" and "active force feedback".

The control unit 30 sets the set force value, SF to the controller to be zero (SF=0). It determines the amplification in the inner, force control loop 112 (not the set force!) depending on the set force, SF, that is, the resistance that the simulation want the user to experience. This results in that the frictions in the system G(s) is compensated in a varying extent, determined from the loop amplification.

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Example: With high amplification the user experience zero force. With low amplification, the user experience high resistance. In this way the friction will be what the user experience as resistance and a "passive force-feedback" is accomplished, see Fig. 9.

5 Thus is:

$$K=C1*(1-C2 * DF)$$

wherein:

K = Loop amplification, F3(s)

10 DF = Demand Force,

C1 and C2 are constants.

To provide an "active force feedback" the Demand Force, DF/Set Force value, SF, must be controlled. In this case it is the longitudinal motor, which causes the resistance, see Fig.

15 10.

The user inserts the instrument for the endovascular operation, for example catheters, balloons, wires and the like, through the entry pipe 24 in the opening 22. The instrument is led through the interconnecting member 26 into the carriages 16A-16C, which carriages
20 16A-16C detects the instruments and grab hold of the instrument to be able to measure the movement of the instrument and give feedback to that movement.

The interface device with associated control unit 30 has the following function:

- 25 • Measure the movement of at least three separate nested instruments. These instruments are real, with one modification, soft and curved points are cut off. The measured movement consists of the longitudinal direction and the direction of rotation of the instrument point.
- Measure a pedal position, depressed and released.
- 30 • Measure the flow from a contrast syringe.
- Measure the pressure from a pressure pump for balloon blasting.
- Send measured values to the simulation unit 90.
- Receive forces and torque on the instruments respectively from the simulation unit 90.
- 35 • Give force-feedback in longitudinal direction and the direction of rotation of the instruments according to received forces and torques.
- Measure the signal from a special instrument.

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A control program for a system and the device is described in a parallel application, entitled "AN INTERVENTIONAL SIMULATOR CONTROL SYSTEM" (SE 0203567-3) by the same applicant and incorporation herein through reference.

- 5 The present invention has now been described by means of the best embodiment and modifications thereof. However the invention is not limited to the illustrated embodiments, but variants and other modifications are also possible within the scope of the claims. It is also possible to connect several devices to one or several PC's for simulating one simultaneous interventional procedure.

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REFERENCE SIGNS

	processor unit	10
	communication unit	12
5	power supply	14
	carriage	16
	first, second, third	16A-16C
	transmission	18
	track	20
10	opening	22
	entry pipe	24
	interconnecting members	26
	first, second, third	26A-26C
	cover	28
15	control unit	30
	chassis	32
	wheel	34
	suspended plate	38
	force sensor	40
20	central wall	42
	locking member	44
	outlet	46
	detecting member	48
	central unit	50
25	torque wheel	52
	gear ring	54
	torque motor	56
	torque motor hub	58
	torque motor gear wheel	60
30	lock wheel	62
	lock motor	64
	lock motor hub	66
	lock motor gear wheel	68
	collet	70
35	collet seat	72
	crank block	74
	speed control loop	86
	position control loop	88

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simulation unit	90	
device	100	
force feedback control loop	102	
IR diode	104	
5 IR phototransistor	106	
tool passage	108	
light channel	110	
inner force control loop		112

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CLAIMS

1. A device (100) in a simulation system for simulating an interventional operation, said device (100) being arranged to receive a number of real instruments, preferably at
5 least two real instruments,
the device (100) comprising:
a number of moveable carriages (16A-16C) corresponding to the number of said real instruments,
a track (20),
10 an interconnecting member (26)
wherein said interconnecting member (26) interconnects said carriages (16A-16C) serially, each carriage (16A-16C) being provided with an opening for enabling reception of said real instruments, each carriage (16A-16C) further comprising members to receive and lock at least one real instrument, and members for receiving a movement
15 from said instrument and generating a force, fed back to said real instrument with respect to a simulation characteristic.
2. The device of claim 1, wherein said opening (22) is provided within said interconnecting member (26).
20
3. The device of claim 1, wherein said interconnecting member (26) is a telescopic pipe.
4. The device of claim 1, wherein each carriage (16A-16B) comprises a detecting arrangement (48) for detecting the type of said real instrument inserted through said
25 interconnecting member (26).
5. The device of claim 1, wherein said device (100) is connected to a control unit (30) to measure the movement of said carriages (16A-16C) and control said movement by means of a speed control loop (86) and a position control loop (88).
30
6. The device of claim 1, wherein said carriages (16A-16C) are arranged to move along said track (20).
7. The device of claim 1, wherein said carriage (16) has an actual position and a
35 simulated position, which actual carriage position determines the simulated carriage position from a scale table.

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8. The device of claim 1, wherein said carriage (16A-16C) is connected through a transmission (18) for driving along said track (20).
9. The device of claim 1, wherein said carriage (16) is provided with a crank block (74),
5 which is arranged in a torque wheel (52).
10. The device of claim 1, wherein said crank block (74) is provided with a mating surface, which is pressed towards a collet (70) that grips the instrument wire.
- 10 11. The device of claim 1, wherein the force between a suspended plate (38) and a chassis (32), which is arranged on said carriage (16A-16C), is measured by means of a force sensor (40).
12. The device of claim 1, wherein said carriage (16) is provided with a detecting member
15 (48), which detects presence of an instrument in the carriage (16).
13. The device of claim 1, wherein said detecting member (48) is arranged to detect the type of each real instrument.
- 20 14. The device of claim 13, wherein said real instruments are categorized into said types with respect to at least one of the following characteristics; thickness, color, structure, material, identity and/or bar-code.
15. The device of claim 12, wherein said detecting member (48) is an optical sensor.
25
16. The device of claim 1, wherein a first interconnecting member (26A) is arranged between said opening (22) and the first carriage (16A), a second interconnecting member (26B) is arranged between the first carriage (16A) and the second carriage (16B) and a third interconnecting member (26C) is arranged between the second
30 carriage (16B) and the third carriage (16C).
17. The device of claim 1, comprising a processing unit (10) for measuring a longitudinal movement and a movement of rotation, of the instrument.
- 35 18. The device of claim 1, comprising a processing unit (10), which provides force-feedback in the longitudinal direction and in the direction of rotation, of the real instrument.

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19. The device of claim 1, wherein an end or part of said real instrument is simulated.
20. The device of claim 1, comprising a locking member (44), for clamping an instrument, which locking member (44) is attached to a central wall (42).
- 5
21. The device of claim 1, wherein said locking member (44) comprises a member for applying a torque.
22. The device of claim 1, wherein said crank block (74) is provided inside a torque wheel (52), which crank block (74) moves in longitudinal direction and is fixed in the direction of rotation, relatively to the torque wheel (52).
- 10
23. A method of simulating a interventional operation by means of a device (100) in a simulation system, said device (100) being arranged to receive a number of real instruments, preferably at least two real instruments, the device (100) comprising:
- 15
- a number of moveable carriages (16A-16C) corresponding to the number of said instruments,
- a track (20),
- an interconnecting member (26),
- 20
- the method comprising the steps of inserting a number of real instruments into said device (100), receiving said real instruments by each carriage, which are interconnected serially, by receiving and locking at least one instrument, each carriage (16A-16C) further comprising members for receiving a movement from said real instrument and generating a force fed back to said real instrument with respect to a
- 25
- simulation characteristic.
24. A device according to any one of claims 1-22 in a simulator system, preferably an interventional procedure simulator system, comprising at least a first and a second displaceable member (16A-16C), a control system comprising:
- 30
- a first controller (F1(s)), controlling the speed of said first displaceable member (16A-16C) towards a set value (CDV),
 - a second controller (F2(s)), for combining an error in a position (CAP) and a speed of said second, previous displaceable member (PCAV) to a set speed for the first member, wherein the second controller (F2) controls $CDV = C1 * (CAP - PCAP) + C2 * PCAV$, wherein C1 and C2 are constants.
- 35
25. A device according to any one of claims 1-22 in a simulator system, preferably an interventional procedure simulator system, comprising an arrangement for detecting a real instrument to be simulated, wherein said arrangement comprises identification

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means for identifying said real instrument.

26. The interventional procedure of claim 25, wherein said arrangement for detecting an instrument, comprises at least one IR diode (104) and at least one IR phototransistor (106).

27. The interventional procedure of claim 25, wherein said identification means consists of at least one of thickness, color, structure, material of said real instrument, identity and/or bar-code.

10

28. A device according to any one of claims 1-22 in a simulator system, preferably an interventional procedure simulator system, further comprising members to receive and lock a real instrument to be simulated, a control unit (30) comprising a force sensor (40), wherein said control unit (30) controls towards a demand force value (DF), and a force that a user experiences in the instrument is measured with the force sensor (40), and a signal from the force sensor (40) is fed back in a force feedback control loop (102) towards a set force.

15

29. A device according to any one of claims 1-22 in a simulator system, preferably an interventional procedure simulator system, comprising an arrangement for generating a resistance in a simulated real instrument, the arrangement comprising a control unit (30), a force sensor (40), a force feedback control loop (102) for controlling an actuator device for driving an instrument receiver member (16) in a direction, and an inner force control loop (112) wherein said force sensor is arranged for measuring said resistance, a signal from the force sensor is fed back in said inner force control loop (112) that controls, with a loop amplification (K) provided by said control unit, towards a set force value (SF) provided by said control unit and said inner force control loop (112) controlling said actuator.

20

25

30. The simulator system of claim 29, wherein said control unit (30) controls said loop amplification (K) to achieve a said resistance.

30

31. The simulator system of claim 29 or 30, wherein said control unit (30) controls said set force (SF) to achieve a said resistance.

35

32. A device according to any one of claims 1-22 in a simulator system, preferably an interventional procedure simulator system, comprising an arrangement for generating a resistance in an simulated real instrument, an arrangement for receiving and fixing a part of a real instrument in a device for measuring instrument movement and feeding

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back a force to said real instrument, said arrangement comprising a member for clamping said real instrument.

- 5 33. The arrangement of claim 32, comprising a crank block (74), which is arranged in a torque wheel (52), said crank block (74) being movable in a longitudinal direction inside said torque wheel (52).
34. The arrangement of claim 33, wherein said crank block (74) is provided with a mating
10 surface, which is pressed towards a collet (70) that grips said instrument part.

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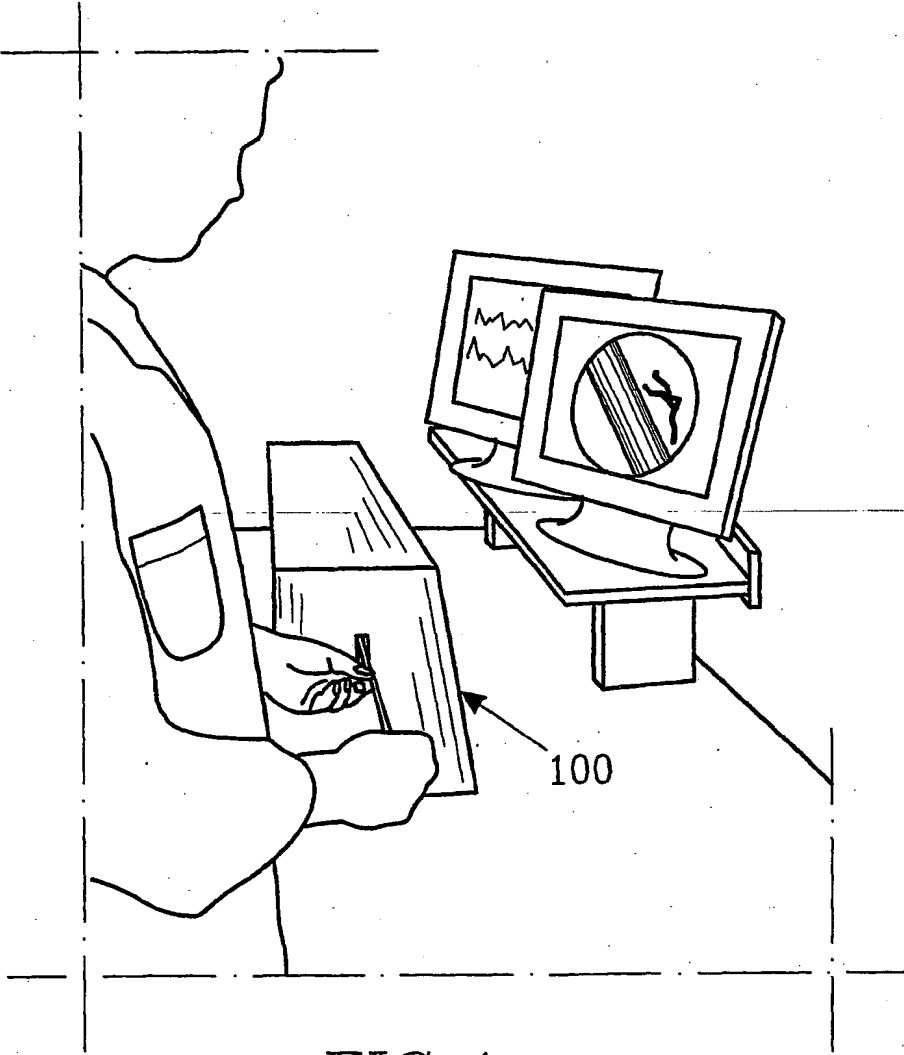


FIG.1

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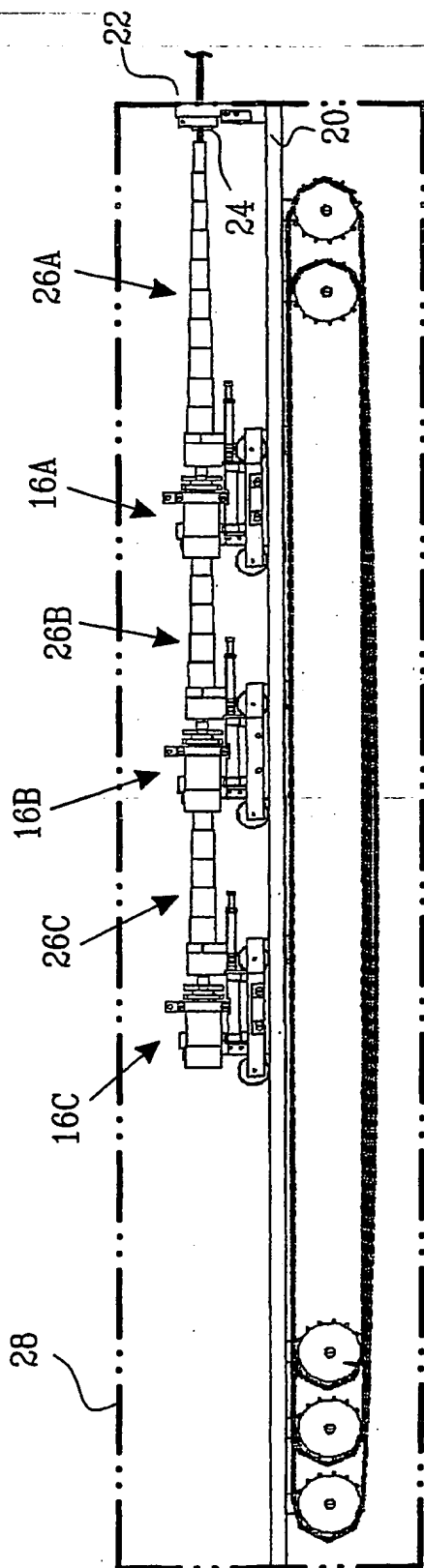


FIG. 2

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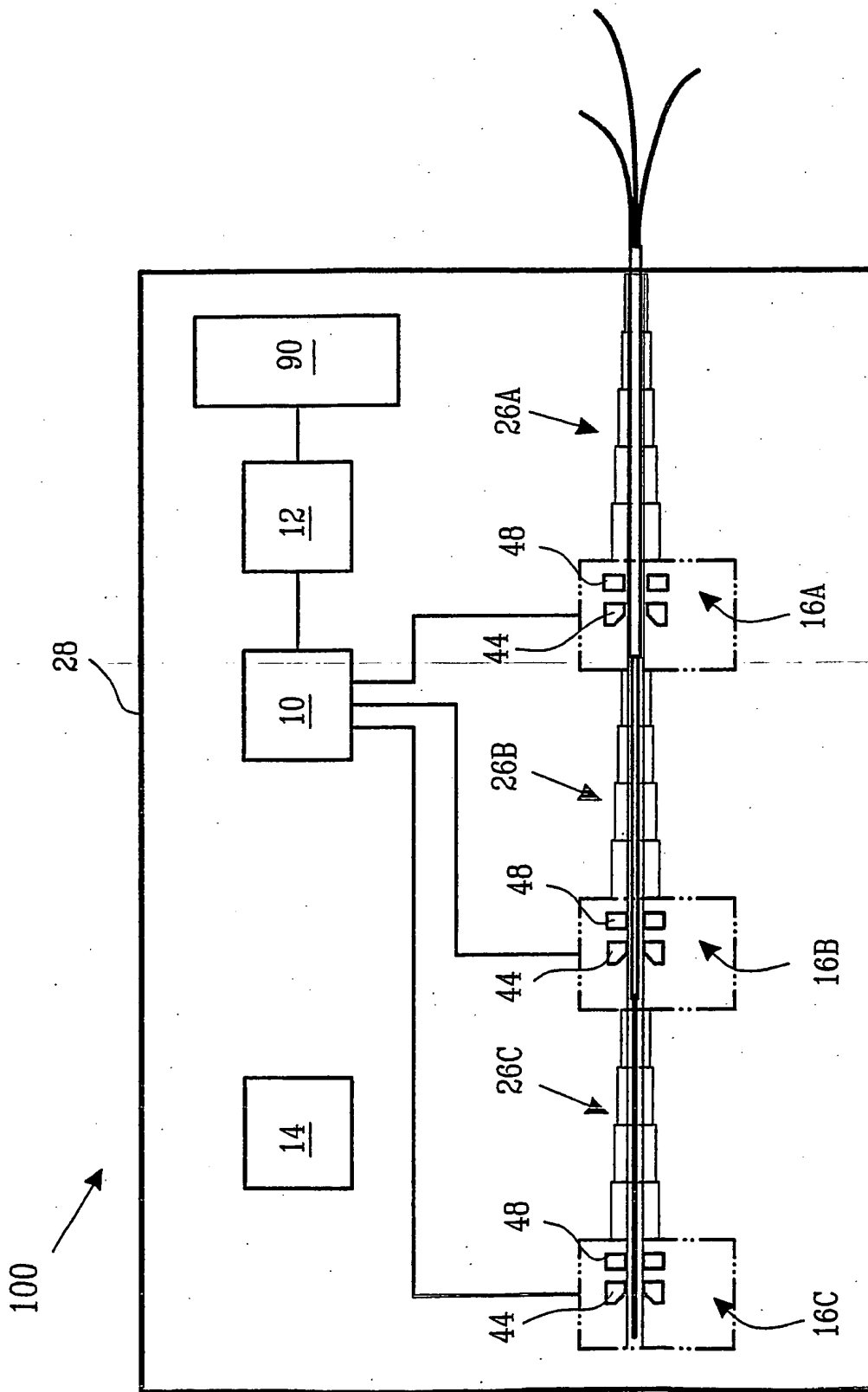


FIG.3

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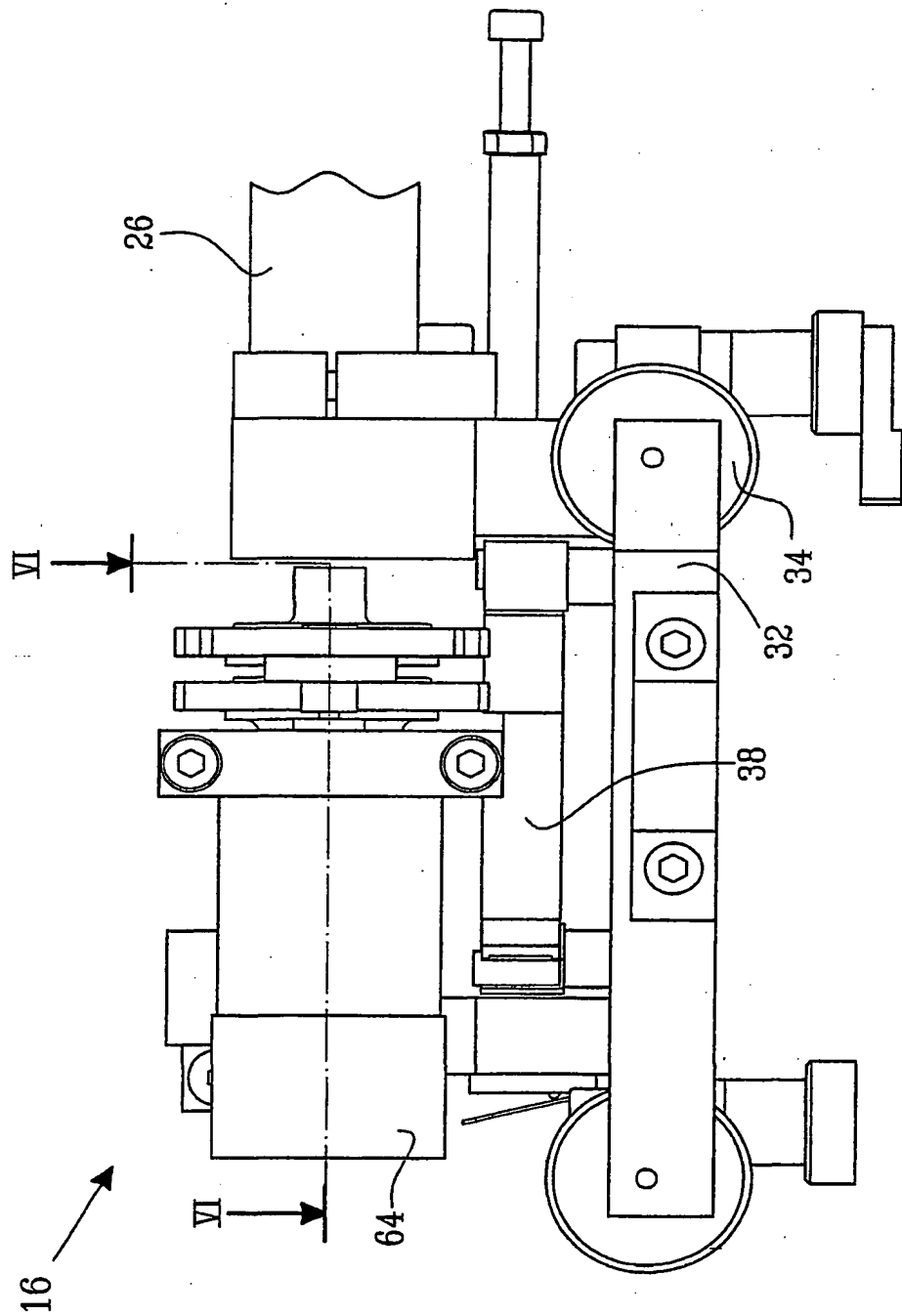


FIG. 4

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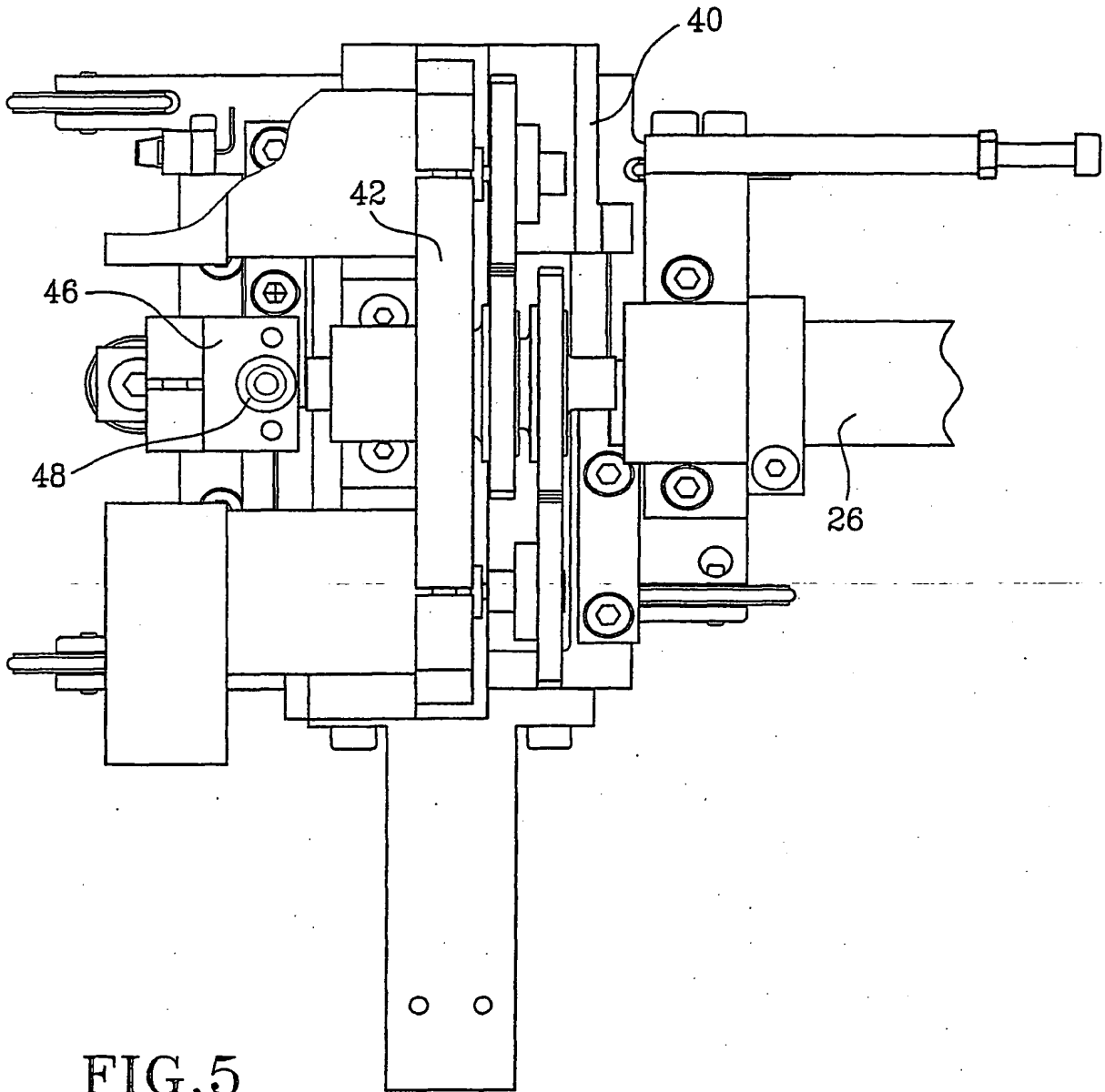


FIG.5

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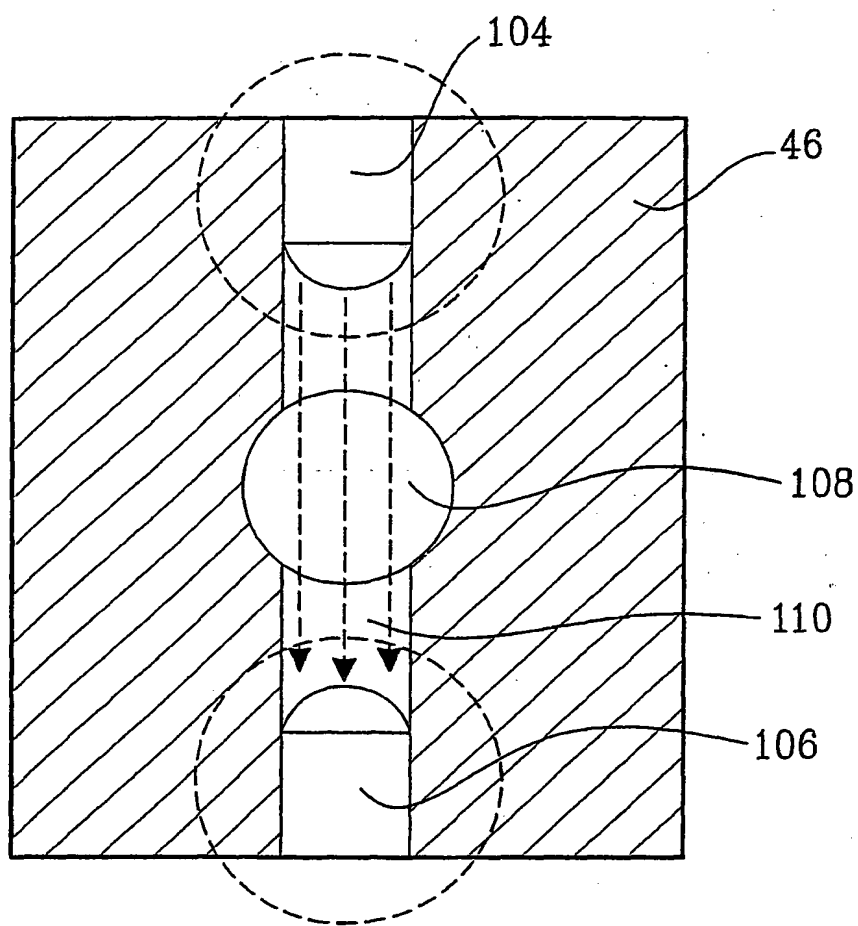


FIG.6

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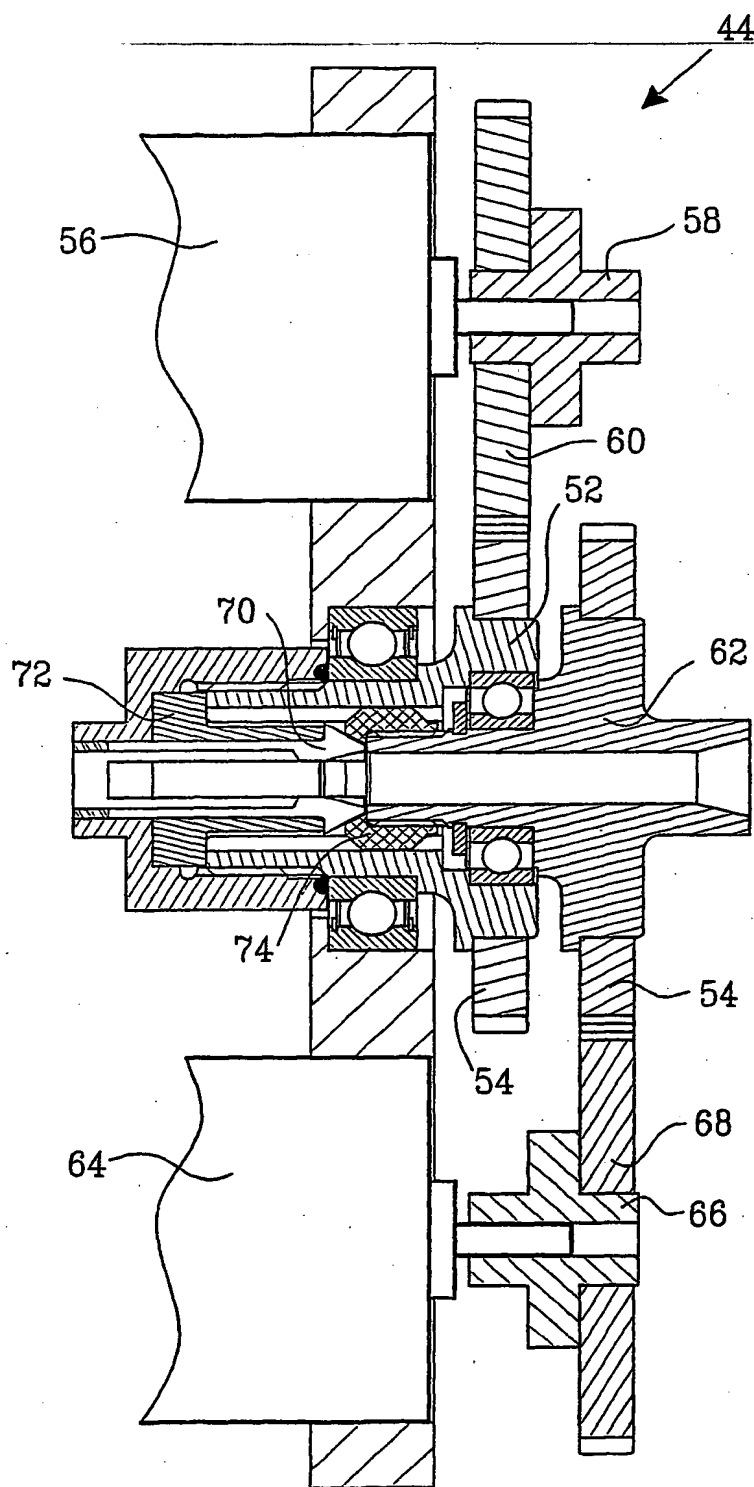


FIG. 7

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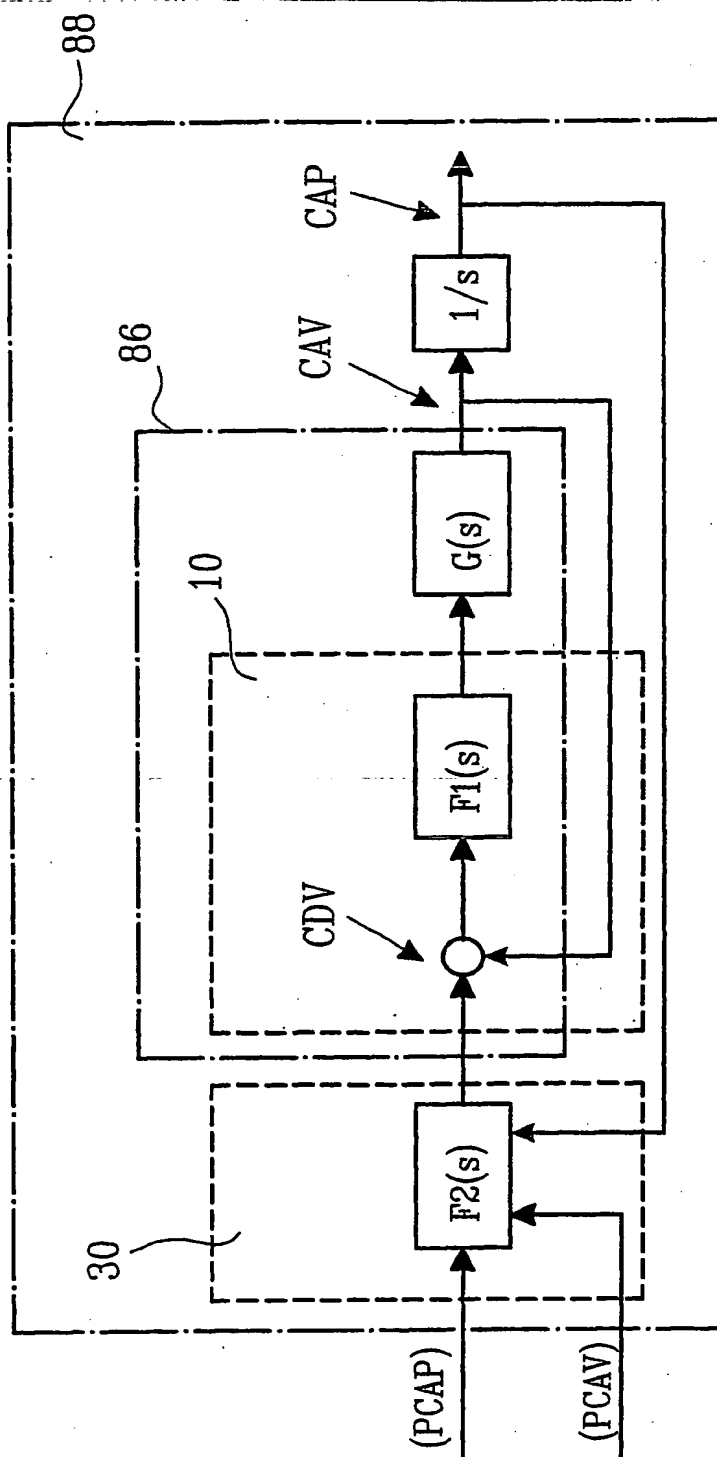


FIG. 8

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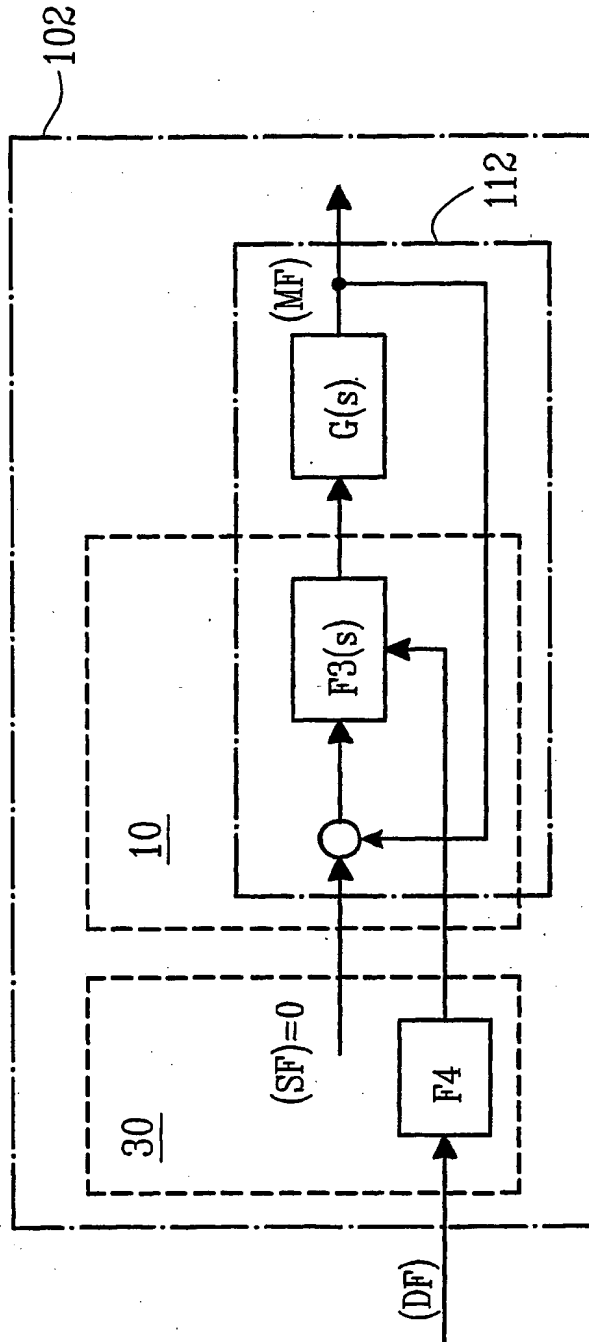


FIG. 9

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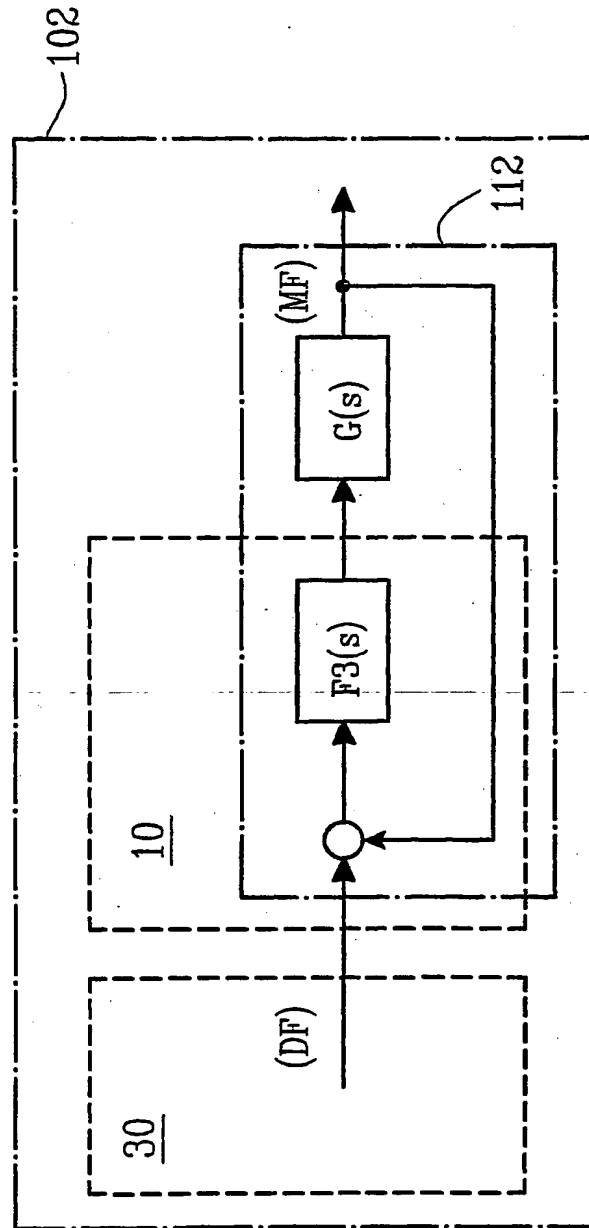


FIG.10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2003/001891

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: G09B 23/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9939317 A1 (HT MEDICAL SYSTEMS, INC.), 5 August 1999 (05.08.1999), page 11, line 1 - line 17; page 29, line 7 - page 37, line 6, figures 15-17	1,2,3,16,23
A	--	24
A	EP 0970714 A2 (MITSUBISHI DENKI KABUSHIKI KAISHA), 12 January 2000 (12.01.2000), page 7, line 10 - page 9, line 20	1,2,3,16,23, 24

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

8 April 2004

Date of mailing of the international search report

15-04-2004

Name and mailing address of the ISA/

Swedish Patent Office

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INTERNATIONAL SEARCH REPORT
Information on patent family members

27/02/2004

International application No.

PCT/SE 2003/001891

WO	9939317	A1	05/08/1999	AU	2242099	A	16/08/1999
				EP	1103041	A	30/05/2001
				GB	0021185	D	00/00/0000
				GB	0302744	D	00/00/0000
				GB	2349730	A,B	08/11/2000
				GB	2384613	A,B	30/07/2003
				JP	2003525639	T	02/09/2003
				US	2001016804	A	23/08/2001
				US	2001026551	A	04/10/2001
				AU	4718499	A	17/01/2000
				EP	1123172	A	16/08/2001
				EP	1369194	A	10/12/2003
				US	6053675	A	25/04/2000
				WO	0000314	A	06/01/2000

EP	0970714	A2	12/01/2000	JP	2000042117	A	15/02/2000
				US	6375471	B	23/04/2002

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2003/001891

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1, 2, 3, 16, 23, 24**

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
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Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present application has been considered to contain 9 inventions which are not linked such that they form a single general inventive concept, as required by Rule 13 PCT for the following reasons:

Claims 1 and 23:

The closest prior art has been identified as:

D1: WO 9939317 A1

Document D1 discloses a device for a simulation system for simulating medical procedures (i.e. interventional operations). In D1 it is possible to insert nested mock or actual instrument into the device and simulate movements and rotation for every instrument, (see page 11 line 1- 17). From D1, see page 29 line 7 - page 37 line 6 and figures 15-17, it is known that the device contains movable carriages corresponding to the number of mock or actual instruments, that the carriages can move on tracks, one or several interconnecting members which interconnects the carriages serially, every carriage has an opening for enabling reception of an instrument, each carriage comprising members for receiving and locking one instrument, and members for receiving a movement from said instrument with respect to a simulation characteristic.

The invention according to the independent claims 1 and 23 lacks novelty since all the technical features described in these claims are known from D1.

Claims 2-22:

The following separate inventions were identified for the dependent claims 1-22:

INV1: Claims 2, 3, 16 relates to the interconnecting member.

INV2: Claims 4, 12-14, 15 are directed to a detecting arrangement for detecting the type of instrument.

INV3: Claims 5, 7, 17, 18 are directed to a control unit and a processing unit for measuring and controlling the instruments position and movement.

INV4: Claims 6, 8 relates to transmission and tracks for the carriages.

.../...

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INV5: ~~Claims 9-11, 20-22 are directed to mechanical details on the carriages.~~

INV6: Claim 19 relates to a simulated end part on the real instrument.

A search for a special technical feature among claims 2-22 of the present application did not reveal a unifying, novel technical feature that define a contribution over the prior art. Consequently it appears that, a posteriori, claims 2-22 includes 6 different inventions, and INV2-INV6 do not satisfy the requirements of unity of invention and will therefore not be taken under consideration in this report.

The further investigation will therefore be based on INV1 (claims 2,3,16).

From D1 it is known that the opening is provided with an interconnecting member, that the interconnecting member could be telescopic, and that each carriage is connected to an interconnecting member.

The invention according to the independent claims 2, 3 and 16 lacks novelty since all the technical features described in these claims are known from D1.

Claims 24-34:

Claims 24-34 are treated as belonging to claim 2.

The following separate inventions were identified for the dependent claims 24-34:

INV7: Claim 24 relates to a control system comprising a first and a second controller for controlling the speed of a first and a second displaceable member.

INV8: Claims 25-27 are directed to identification means for detecting and identifying an instrument.

INV9: Claims 28-34 relates to an arrangement for measuring, generating and controlling forces and resistances to or from a simulated instrument.

A search for a special technical feature among claims 24-34 of the present application did not reveal a unifying, novel technical feature that define a contribution over the prior art. Consequently it appears that, a posteriori, that claims 24-34 includes 3 different inventions, and INV8-INV9 do not

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satisfy the requirements of unity of invention and will therefore not be taken under consideration in this report.

A partial search has been carried out, which relates to INV1 and INV7 (including claims 1, 2, 3, 16, 23 and 24) mentioned above.

The applicant is invited to pay additional fees for INV2-INV6 and INV8-INV9.

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